Terrestrial Animal Health Standards Commission Report

March 2008

APPENDIX 3.x.x.

GENERAL GUIDELINES ~~FOR~~ ON THE APPLICATION OF COMPARTMENTALISATION

Article 3.x.x.1.

Introduction and objectives

The guidelines in this ~~appendix~~ Appendix provide a structured framework for the application and recognition of *compartments* within countries or *zones*, based on the provisions of Chapter 1.3.5. with the objective to facilitate trade in *animals* and products of animal origin and as a tool for *disease* management.

Establishing and maintaining a disease-free status for an entire country may be difficult, especially in the case of *diseases* that can easily cross international boundaries. For many *diseases*, OIE Members ~~Countries~~ have traditionally applied the concept of zoning to establish and maintain an animal *subpopulation* with a different animal health status within national boundaries.

Chapter 1.1.1. defines a *compartment* as "~~one~~ an *animal subpopulation* contained in one or more *establishments* under a common biosecurity management system ~~containing an animal *subpopulation*~~ with a distinct health status with respect to a specific *disease* or specific *diseases* for which required surveillance, control and biosecurity measures have been applied for the purpose of *international trade*."

The essential difference between zoning and compartmentalisation is that the recognition of *zones* is based on geographical boundaries whereas the recognition of *compartments* is based of management practices and biosecurity. However, spatial considerations and good management practices play a role in the application of both concepts.

Compartmentalisation is not a new concept for *Veterinary Services*; in fact, it has been applied for a long time in many *disease* control programmes that are based on the concept of *disease*-free herds/flocks.

The fundamental requirement for compartmentalisation is the implementation and documentation of management and biosecurity measures to create a functional separation of ~~*establishments*~~ *subpopulations* ~~and allows the *Veterinary Services* to make a clear epidemiological differentiation to be made between *subpopulations* of differing health status~~.

For example, a ~~confinement operation for a poultry or swine~~ an animal production operation in an infected country or *zone* might have biosecurity measures and management practices that result in negligible risk from *diseases* or agents. The concept of a *compartment* extends the application of a 'risk boundary' beyond that of a geographical interface and considers all epidemiological factors that can help to create an effective *disease*-specific separation between *subpopulations*.

In *disease*-free countries or *zones*, *compartments* preferably should be defined prior to the occurrence of a *disease outbreak*. In the event of an *outbreak* or in ~~endemic~~ infected countries or *zones*, compartmentalisation may be used to facilitate trade.

For the purpose of *international trade*, *compartments* must be under the ~~direct control and~~ responsibility of the *Veterinary ~~Administration~~ Authority* in the country. For the purposes of this ~~appendix~~ Appendix, compliance by the Members with Chapters 1.1.2. and 1.3.3. ~~are~~ is an essential prerequisite.

Article 3.x.x.2.

Principles for defining a compartment

A *compartment* may be established with respect of a specific *disease* or *diseases*. A *compartment* must be clearly defined, indicating the location of all its components including *establishments*, as well as related functional units (such as feed mills, *slaughterhouses*, rendering plants, etc.), their interrelationships and their contribution to an epidemiological separation between the animals in a *compartment* and *subpopulations* with a different health status. The definition of *compartment* may revolve around *disease* specific epidemiological factors, animal production systems, biosecurity practices infrastructural factors and surveillance. ~~and similar functional demarcations~~.

Article 3.x.x.3.

Separation of a compartment from potential sources of infection

The management of a *compartment* must provide to the *Veterinary ~~Administration~~ Authority* documented evidence on the following:

a) Physical or spatial factors that affect the status of biosecurity in a compartment

While a *compartment* is primarily based on management and biosecurity measures, a review of geographical factors is needed to ensure that the functional boundary provides adequate separation of a *compartment* from adjacent animal populations with a different health status. The following factors should be taken into consideration in conjunction with biosecurity measures and, in some instances, may alter the degree of confidence achieved by general biosecurity and surveillance measures:

i) *disease* status in adjacent areas and in areas epidemiologically linked to the *compartment*;

ii) location, *disease* status and biosecurity of the nearest *epidemiological units* or other epidemiologically relevant premises. Consideration should be given to the distance and physical separation from:

- flocks or herds with a different health status in close proximity to the *compartment*, including wildlife and their migratory routes;

- *slaughterhouses*, rendering plants or feed mills;

- markets, fairs, agricultural shows, sporting events, zoos, circuses and other points of animal concentration.

b) Infrastructural factors

Structural aspects of the *establishments* within a *compartment* contribute to the effectiveness of its biosecurity. Consideration should be given to:

i) fencing or other effective means of physical separation;

ii) facilities for people entry including access control, changing area and showers;

iii) *vehicle* access including washing and *disinfection* procedures;

iv) *unloading* and *loading* facilities;

v) isolation facilities for introduced animals;

vi) facilities for the introduction of material and equipment;

vii) infrastructure to store feed and veterinary products;

viii) disposal of carcasses, manure and waste;

~~viii~~ix)water supply;

~~i~~x) ~~physical~~ measures to prevent exposure to living mechanical or biological vectors such as insects, rodents and wild birds;

xi) air supply;

xii) feed supply/source.

More detailed recommendations for certain *establishments* can be found in Sections 3.2., 3.3. and 3.4. of the *Terrestrial Code*.

c) Biosecurity plan

The integrity of the *compartment* relies on effective biosecurity. The management of the *compartment* should develop, implement and monitor a comprehensive *biosecurity plan*.

The *biosecurity plan* should describe in detail:

i) potential pathways for introduction and spread into the *compartment* of the agents for which the *compartment* was defined, including animal movements, rodents, fauna, aerosols, arthropods, *vehicles*, people, biological products, equipment, fomites, feed, waterways, drainage or other means. Consideration should also be given to the survivability of the agent in the environment;

ii) the critical control points for each pathway;

iii) measures to mitigate exposure for each critical control point;

iv) standard operating procedures including:

- implementation, maintenance, monitoring of the measures;

- application of corrective actions;
- verification of the process;
- record keeping;

v) contingency plan in the event of a change in the level of exposure;

vi) reporting procedures to the *Veterinary ~~Administration~~ Authority*;

vii) the programme for educating and training workers to ensure that all persons involved are knowledgeable and informed on biosecurity principles and practices;

viii) the surveillance programme in place.

In any case, sufficient evidence should be submitted to assess the efficacy of the biosecurity plan in accordance with the level of *risk* for each identified pathway. The biosecurity risk of all operations of the *compartment* should be regularly re-assessed and documented at least on a yearly basis. Based on the outcome of the assessment, concrete and documented mitigation steps should be taken to reduce the likelihood of introduction of the *disease* agent into the *compartment*.

d) Traceability system

A prerequisite for assessing the integrity of a *compartment* is the existence of a valid traceability system. All animals within a *compartment* should be individually identified and registered in such a way that their history and movements can be documented and audited. In cases where individual identification may not be feasible, such as broilers and day-old chicks, the *Veterinary ~~Administration~~ Authority* should provide sufficient assurance of traceability.

All animal movements into ~~and out of~~ and out of the *compartment* should be ~~certified by the *Veterinary Administration ~~Authority~~* and~~ recorded at the *compartment* level, and when needed, based on a *risk assessment*, certified by the *Veterinary Authority*. Movements within the *compartment* need not be certified but should be recorded at the *compartment* level.

Article 3.x.x.4.

Documentation ~~of factors critical to the definition of a compartment~~

Documentation must provide clear evidence that the biosecurity, surveillance, traceability and management practices defined for a *compartment* are effectively and consistently applied. In addition to animal movement information, the necessary documentation should include herd or flock production records, feed sources, laboratory tests, birth and death records, the visitor logbook, morbidity history, medication and vaccination records, *biosecurity plans*, training documentation and any other criteria necessary for the evaluation of *disease* exclusion.

The historical status of a *compartment* for the *disease(s)* for which it was defined should be documented and demonstrate compliance with the requirements for freedom in the relevant *Terrestrial Code* chapter.

In addition, a *compartment* seeking recognition should submit to the *Veterinary ~~Administration~~ Authority* a baseline animal health report indicating the presence or absence of OIE *listed diseases*. This report should be regularly updated to reflect the current animal health situation of the *compartment*.

Vaccination records including the type of vaccine and frequency of administration must be available to enable interpretation of surveillance data.

The time period for which all records should be kept may vary according to the species and *disease(s)* for which the *compartment* was defined.

All relevant information must be recorded in a transparent manner and be easily accessible so as to be auditable by the *Veterinary ~~Administration~~ Authority*.

Article 3.x.x.5.

Surveillance for the agent or disease

The surveillance system should comply with Appendix 3.8.1. on General Guidelines for Surveillance and the specific guidelines for surveillance for the *disease(s)* for which the *compartment* was defined, if available.

If there is an increased risk of exposure to the agent for which the *compartment* has been defined, the detection level of the internal and external surveillance should be reviewed and where necessary raised. ~~and the level of biosecurity should be raised.~~ At the same time, biosecurity measures in place should be reassessed and increased if necessary.

a) Internal surveillance

Surveillance should involve the collection and analysis of *disease/infection* data ~~such~~ so that the *Veterinary ~~Administration~~ Authority* can certify that the animal~~s~~ *subpopulation* contained in all the *establishments* comply with the defined status of that *compartment*. A surveillance system that is able to ensure early detection in the event that the agent enters a~~n~~ *~~establishment~~ subpopulation* is essential. Depending on the *disease(s)* for which the *compartment* was defined, different surveillance strategies may be applied to achieve the desired confidence in *disease* freedom.

b) External surveillance

The biosecurity measures applied in a *compartment* must be appropriate to the level of exposure of the *compartment*. External surveillance will help identify a significant change in the level of exposure for the identified pathways for *disease* introduction into the *compartment*.

An appropriate combination of active and passive surveillance is necessary to achieve the goals described above. Based on the recommendations of ~~appendix~~ Appendix 3.8.1., targeted surveillance based on an assessment of risk factors may be the most efficient surveillance approach. Targeted surveillance should in particular include *epidemiological units* in close proximity to the *compartment* or those that have a potential epidemiological link with it.

Article 3.x.x.6.

Diagnostic capabilities and procedures

Officially-designated laboratory facilities complying with the OIE standards for quality assurance, as defined in Chapter I.1.2. of the *Terrestrial Manual*, should be available for sample testing. All laboratory tests and procedures should comply with the recommendations of the *Terrestrial Manual* for the specific *disease*. Each laboratory that conducts testing should have systematic procedures in place for rapid reporting of *disease* results to the *Veterinary ~~Administration~~ Authority*. Where appropriate, results should be confirmed by an OIE Reference Laboratory.

Article 3.x.x.7.

Emergency response and notification

Early detection, diagnosis and notification of *disease* are critical to minimisze the consequences of *outbreaks*.

In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, export certification should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.2.

In case of ~~a suspicion or~~ an occurrence of any ~~OIE *listed disease*~~ infectious *disease* not present according to the baseline animal health report of the *compartment* referred to in ~~article~~ Article 3.x.x.4., the management of the *compartment* should notify the *Veterinary ~~Administration~~ Authority*, and initiate a review ~~as this may~~ to determine whether there has been ~~indicate~~ a breach in the biosecurity measures. ~~The *Veterinary Administration* *Authority* should immediately suspend export certification and should notify the importing countries re-assess the biosecurity of the *compartment* and I~~If a significant breach is detected, export certification should be suspended. Trade may only be resumed after the *compartment* has adopted the necessary measures to re-establish the biosecurity level and the *Veterinary ~~Administration~~ Authority* re-approves the *compartment* for trade.

~~In the event of suspicion of occurrence of the *disease* for which the *compartment* was defined, export certification should be immediately suspended. If confirmed, the status of the *compartment* should be immediately revoked and *importing countries* should be notified following the provisions of Chapter 1.1.2.~~

~~Positive findings of the disease(s) for which the compartment has been defined, should be immediately notified following the provisions of Chapter 1.1.2.~~

Article 3.x.x.8.

Supervision and control of a compartment

The authority, organisation, and infrastructure of the *Veterinary Services*, including laboratories, must be clearly documented in accordance with the chapter on the evaluation of *Veterinary Services* of the OIE *Terrestrial Code*, to provide confidence in the integrity of the *compartment*.

The *Veterinary ~~Administration~~ Authority* has the final authority in granting, suspending and revoking the status of a *compartment*. The *Veterinary ~~Administration~~ Authority* should continuously supervise compliance with all the requirements critical to the maintenance of the *compartment* status described in this ~~appendix~~ Appendix and ensure that all the information is readily accessible to the *importing countries*. Any significant change should be notified to the *importing country*.